IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

NOS. 14-2071 and 15-1250
(consolidated)

American Sales Co., et al.,
Plaintiffs-Appellants,

v.

Warner-Chilcott Co., LLC, et al.,
Defendants-Appellees.

On Appeal from the United States District Court
For the District of Rhode Island (No. 1:13-md-02472-S-PAS)

BRIEF OF FEDERAL TRADE COMMMISSION AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS-APPELLANTS

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INTRODUCTION

Generic drug competition saves consumers billions of dollars a year. Those savings come at the expense of monopoly profits otherwise reaped by brand-name drug manufacturers. To encourage generic drug competition, Congress established a mechanism that enables would-be generic manufacturers to challenge the patents associated with brand-name drugs, often triggering litigation. In some cases, the parties settle such litigation and structure the settlement so that the generic agrees to stay out of the market for a time in exchange for compensation from the brand company. Through such "reverse payments," the brand company and generic challenger can preserve the brand's monopoly profits, which the brand effectively shares with the generic challenger. The agreement can thus prevent competition, maintain high prices, and harm consumers.

In *FTC v. Actavis*, 133 S. Ct. 2223 (2013), the Supreme Court reaffirmed that traditional antitrust principles apply to patent litigation settlements and that patent law confers no broad immunity on parties to such settlements. Applying that principle, the Court held that a brand-name drug manufacturer's payment to a generic competitor can violate the antitrust laws under the rule of reason. The question in this case is whether that holding depends on the specific form of the compensation the brand company pays the generic to stay out of the market. As explained below, it does not.

While early reverse payment cases often involved outright cash transfers, brand companies today, after years of antitrust challenges, frequently use payments in kind to induce generic rivals to stay out of the market. Here, plaintiffs allege that brand-name drug manufacturer, Warner Chilcott, used various non-cash forms of payment to compensate its generic rivals for holding back on offering generic equivalents to Loestrin 24, an oral contraceptive. For example, generic company Watson allegedly agreed to drop its patent challenge and stay out of the market for a time in exchange for, *inter alia*, Warner Chilcott's promise that, when Watson finally *did* enter, Warner Chilcott would refrain from competing with its own "authorized generic" product — *i.e.*, the brand-name drug, but marketed as a generic. This arrangement allegedly denied consumers the opportunity to purchase generic Loestrin 24 for several years and then, even after a generic version finally became available, ensured that consumers would pay more for it than if the two companies had offered competing generic products. As alleged, therefore, the arrangement was a win-win for the parties and a loss for consumers.

The district court nonetheless dismissed this case because the consideration Warner Chilcott paid its rivals was in kind rather than in cash. That was error. *Actavis* reflects a core antitrust concern that agreements between competitors to prolong and share monopoly profits are likely to thwart the competitive process and raise consumer prices. That concern arises whether cash or non-cash forms of

compensation are used to accomplish this anticompetitive objective. If accepted, the district court's narrow reading of *Actavis* would enable parties to avoid antitrust scrutiny of anticompetitive reverse-payment settlements simply by avoiding the use of cash. That limitation would illogically elevate form over economic substance.

INTERESTS OF THE FEDERAL TRADE COMMISSION

The Federal Trade Commission is an independent agency charged with promoting a competitive marketplace and protecting consumer interests. *See* 15 U.S.C. § 41 *et seq*. It has substantial experience concerning the balance between antitrust and intellectual property laws.[1] As exemplified by the *Actavis* litigation,

[1] *See, e.g.*, Federal Trade Comm'n, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011) (https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf); U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* (2007) (https://www.ftc.gov/sites/default/files/documents/reports/antitrust-enforcement-and-intellectual-property-rights-promoting-innovation-and-competition-report.s.department-justice-and-federal-trade-commission/p040101promotinginnovationandcompetitionrpt0704.pdf).; FTCommission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (www.ftc.gov/os/2003/10/innovationrpt.pdf); U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* (Apr. 6, 1995) (http://www.justice.gov/atr/public/guidelines/0558.pdf)

the Commission also exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry.

Of particular relevance, the Commission has used its law enforcement authority to challenge patent settlements of the type at issue here.[2] In 2002, the Commission also conducted a comprehensive study of generic drug entry.[3] And since January 2004, it has reviewed and reported on drug-patent settlements, which drug companies are now required to file with the Commission. *See* 21 U.S.C. § 355 note. In 2011, the Commission published the results of a comprehensive empirical study, requested by Congress, of the competitive effects of authorized generics. *See* FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), (*AG Report*) (analyzing data and business documents from industry and commercial sources, including from more than 100 brand and generic companies), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

The Commission has submitted briefs as amicus curiae in a number of proceedings concerning the legality of reverse-payment agreements. *E.g.*, *In re*

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[2] *See, e.g.*, *Actavis*, 133 S. Ct. 2223; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (overruled in relevant part in *Actavis*); First Amended Complaint, *FTC v. Cephalon, Inc.*, No. 08-2141, Doc. No. 40 (E.D. Pa. filed Aug. 12, 2009).

[3] *See* Federal Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration* (July 2002) (*Generic Drug Study*), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

Lamictal Direct Purchaser Antitrust Litig., No. 14-1243, Brief of the Federal Trade Commission as Amicus Curiae Supporting Plaintiffs-Appellants and Urging Reversal (3d Cir. Apr. 28, 2014). Courts, including the Supreme Court and courts of appeals, have relied on FTC studies when resolving legal and policy issues.[4] Pursuant to Fed. R. App. P. 29(a), the Commission respectfully submits this brief.

STATEMENT OF THE CASE

1. Pharmaceutical Patents, Generic Entry, and the Hatch-Waxman Amendments

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended, 21 U.S.C. § 301 *et seq.*, the manufacturer of a new drug must obtain approval from the Food and Drug Administration (FDA) of a new drug application (NDA) before marketing the drug. 21 U.S.C. § 355(b).[5] A drug approved under the lengthy and costly NDA process is often referred to as a "brand-name" drug. *See generally Caraco*, 132 S. Ct. at 1675-76.

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[4] *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012) (citing FTC study on generics); *Granholm v. Heald*, 544 U.S. 460, 466–68, 490–92 (2005) (FTC study of Internet wine sales); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 754 n.11, 765-66 n.20 (1976) (citing FTC study concerning drug price advertising restrictions); *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98, 108 n.17 (2d Cir. 2010) (citing FTC study regarding patent litigation success rate for generic challengers).

[5] All references in this brief to Title 21 are to the 2000 version of the United States Code. As used in this brief, "drug" refers to a drug, as defined in 21 U.S.C. § 321(g)(1), that is regulated by the FDA under 21 U.S.C. § 355.

Generic versions of brand-name drugs contain the same active ingredient and, as described below, compete on price with brand-name drugs. Before 1984, a generic drug manufacturer had to complete the same burdensome NDA process as a brand-name drugmaker. In 1984, however, Congress enacted the Hatch-Waxman Amendments to expedite generic entry. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified at various sections of Titles 15, 21, 28, and 35 of the U.S. Code). The Amendments create a streamlined process for a generic manufacturer to obtain approval from FDA of a generic version of a previously introduced brand-name drug using an Abbreviated New Drug Application (ANDA). They also provide both brand and generic companies certain rights and procedures that apply when a company seeks FDA approval to market a generic product before expiration of patents claimed to cover the counterpart brand-name drug. In such cases, the generic applicant must certify in its ANDA that the patent in question is invalid or not infringed by the generic product (or both). This is known as a "paragraph-IV certification." 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see generally Caraco*, 132 S. Ct. at 1677-78.

To expedite resolution of such patent disputes, the Hatch-Waxman Amendments encourage the brand-name manufacturer to respond to a paragraph-IV certification by promptly suing the generic applicant for patent infringement. Such a suit triggers an automatic stay of FDA approval of the generic company's

ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). To encourage generic companies to avail themselves of this process, the Hatch-Waxman Amendments entitle the first filer of an ANDA containing a paragraph-IV certification to a 180-day period of qualified market exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). That exclusivity protects the first filer from price competition from other ANDA filers during its first 180 days on the market, and it also gives that first filer a head start in reaching commercial arrangements with large purchasers. According to the generic pharmaceutical industry's leading trade association, the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." Comments of Generic Pharm. Ass'n (GPhA) to FTC on Authorized Generic Drug Study 2 (Jun. 27, 2006), http://www.ftc.gov/policy/public-comments/2006/06/27/comment-6.

Significantly, however, the 180-day marketing exclusivity does not preclude the branded-drug company from marketing an "authorized generic" (AG), which is manufactured under that company's NDA but sold as a generic without the trademark or brand name. *See Teva Pharm. Indus. v. Crawford*, 410 F.3d. 51, 54 (D.C. Cir. 2005). As discussed below, brand companies have routinely sold authorized generics to stem losses after initial entry by rival generic companies, to the benefit of consumers and at the expense of the generic companies that would

otherwise sell more generic product and at a higher price. *See AG Report* at 12-14, 26-27.[6]

2. The Economics of Generic Entry and Reverse-Payment Agreements

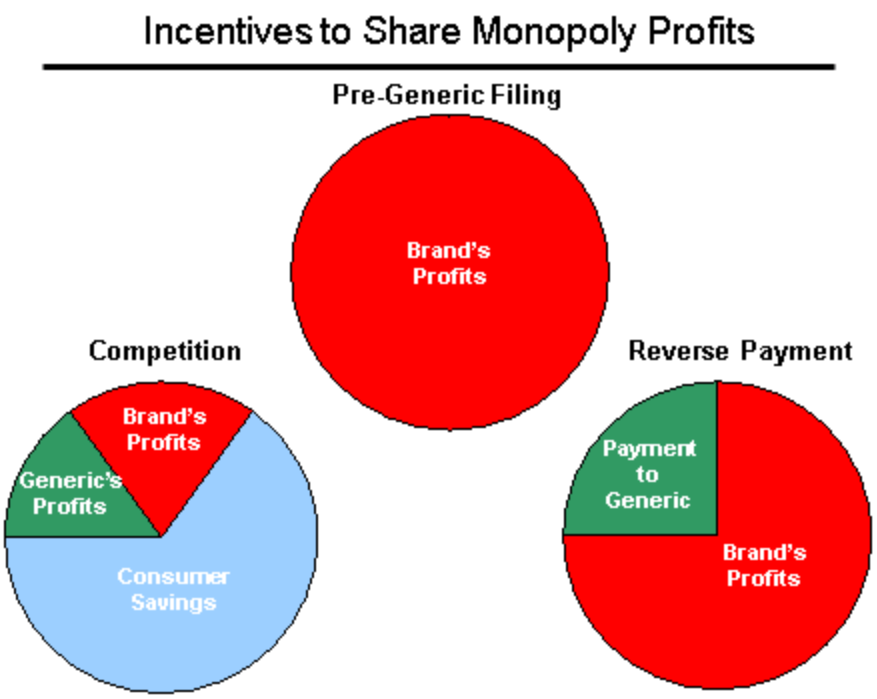
Americans spent nearly $374 billion on prescription drugs in 2014. IMS Inst. for Healthcare Informatics, *Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014*, at 5 (Apr. 2015). Brand-name drugs accounted for 12 percent of total prescriptions but nearly 72 percent of total spending. *Id.* at 45. That disparity arises, *inter alia*, from the monopoly prices that sellers are able to charge for patented drug products.

When the first generic version of a given drug comes on the market, it is priced, on average, nearly 15 percent lower than the brand-name drug. *See AG Report* at ii-iii. Prices fall further when additional generic competitors enter so that, on average, generic prices end up 85 percent lower than the brand-name manufacturers' original prices. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-

[6] As GPhA explained: "To GPhA's knowledge, the brands have launched an authorized generic during every 180-day generic exclusivity period since September 2003." GPhA Letter to Senate Special Committee on Aging at 5 (Jul. 27, 2006), http://gpha.hfwebdev.com/sites/default/files/Smith%20and%20Kohl%20Letter.pdf.

company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf. Eventually, the brand-name drug loses on average about 90 percent of its market share (by unit sales) to its generic competitors. *Id*. Market competition from generic pharmaceuticals thus saves consumers billions of dollars annually. *See* U.S. Gov't Accountability Off., *Report No. GAO-12-371R, Savings from Generic Drug Use* 9-11 (2012), http://www.gao.gov/assets/590/588064.pdf (discussing studies).

Given the significant disparity between monopoly and competitive drug prices, a brand-name manufacturer has both strong incentives to keep its would-be generic competitor on the sidelines and the ability to offer the generic competitor powerful inducements to cooperate. As the diagram below illustrates, while the generic manufacturer will profit if it prevails in paragraph-IV litigation and enters the market, it will gain much less than the brand-name manufacturer stands to lose:



In other words, competition shrinks the total profits the two companies will earn in the aggregate. As a result, both the brand-name and generic manufacturers benefit (at the expense of consumers) if the brand-name manufacturer agrees to share its monopoly profits in exchange for the generic manufacturer's agreement to defer its own entry and thereby keep overall profits at monopoly levels. *See, e.g.*, C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 635-36 (2009). Indeed, such a deal may yield a net benefit to the brand-name manufacturer even if it pays its would-be generic competitors more than they would have earned if they had entered the market. *Actavis*, 133 S. Ct. at 2235

(citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1581 (2006)).

Competitive concerns do not ordinarily arise if a brand-name manufacturer and a generic competitor settle a paragraph-IV patent lawsuit simply by agreeing to a date on which generic entry may occur and go no further. In that case, the agreement is generally unproblematic because it presumably just reflects the parties' risk-adjusted views of likely litigation outcomes. In contrast, settlements of paragraph-IV patent lawsuits can be anticompetitive when the brand-name manufacturer (the patent plaintiff) also *provides compensation* to the generic company (the defendant). The generic company presumably provides some *quid pro quo* for that compensation, regardless of whether the brand-name company has paid the generic in cash or in kind. In the absence of another explanation, that *quid pro quo* may well take the form of the generic company's agreement to stay out of the market for some incremental period in exchange for the brand-name company's payment.

3. The Economics of a "No-AG" Commitment

In the earliest reverse-payment arrangements, the branded-drug company typically compensated the generic company *in cash* for abandoning its patent challenge. As the district court recognized, parties to such arrangements now use less obvious forms of compensation. *See In re Loestrin 24 FE Antitrust Litig.*,

No. 1:13-md-02472-S-PAS, Opinion and Order, at 29 (D.R.I. Sept. 4, 2014) ("slip op.") (describing trend towards non-cash forms of settlement). In many cases, brand-name companies have offered their generic rivals lucrative "side deals," such as the co-promotion and back-up manufacturing arrangements presented in *Actavis*. *See* 133 S. Ct. at 2229. In an increasingly common mechanism, the brand-name enters into a "No-AG commitment" — an agreement not to introduce an AG in competition with the generic manufacturer — in exchange for the generic's agreement to forestall its own entry.[7]

As noted, brand-name companies often introduce AGs to stem the large losses they face once generic entry begins. Competition from an AG reduces the revenues of a first-filer generic company in two distinct ways. First, the AG takes a significant share of generic sales away from the first filer. *AG Report* at 57-59. Second, competition between the first-filer generic and the AG drives down generic drug prices: generic wholesale prices average 70 percent of the pre-entry

[7] *See* Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 Rutgers L.J. 83, 93 (2009) (summarizing myriad ways branded firms avoid paying cash to generics, including through No-AG commitments) (footnotes omitted); *see also* FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act* (FY 2012) at 2 (showing increase in No-AG commitments), http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

brand-name drug price when the first-filer faces an AG, compared to 80 percent of the brand price when it does not. *Id.* at iii, 41-48. Because of these two effects, "the presence of authorized generic competition reduces the first-filer generic's revenues [during the 180-day exclusivity period] by 40 to 52 percent, on average." *Id.* at iii; *see also id.* at 33.[8]

Accordingly, a No-AG commitment is highly lucrative to a first-filer generic company. The FTC's study found that, with a No-AG commitment, "the first-filer's revenue will approximately double" on average, compared to what the first-filer would have made had it faced AG competition. *Id.* at vi; *see also infra* at 27. As the FTC's study further observed, the industry understands that a No-AG commitment can be a win-win for both brand and generic. For example, one branded-drug company's analysis showed that such an agreement could maximize "the combined net present value of both companies' products," resulting in their sharing of supracompetitive profits. *AG Report* at 142. The potential victims in such arrangements are consumers, who end up paying far more than they would in a competitive market.

[8] The effects of an AG continue well after first-filer exclusivity expires, as "[r]evenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53 percent and 62 percent lower when facing an [authorized generic]." *Id.* at iii.

4. The Supreme Court's Decision in *FTC v. Actavis* and the Current Litigation

In *Actavis*, the Supreme Court held that reverse-payment patent settlements can violate the antitrust laws and should be evaluated under the rule of reason. 133 S. Ct. at 2237-38. The FTC's complaint in that case alleged that the brand-name manufacturer of the testosterone-replacement drug AndroGel had agreed, through various side deals, to pay two generic companies in exchange for their agreements to stay off the market for nine years. The district court dismissed the complaint, and the Eleventh Circuit affirmed. It reasoned that the agreements were "immune from antitrust attack" if their anticompetitive effects were all within "the scope of the exclusionary potential of the patent." *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

The Supreme Court reversed, rejecting this so-called "scope-of-the-patent" test and its resulting immunity for settlement agreements that do not exceed the exclusionary potential of the patent. 133 S. Ct. at 2230. The Court explained that its longstanding approach to assessing whether agreements between a patentee and potential competitors violate the antitrust laws considers "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Id.* at 2231. The Court explained that a reverse payment "in effect amounts to a purchase by the patentee of the exclusive right to

sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* at 2234. The payment "simply keeps prices at patentee-set levels" while "dividing that return between the challenged patentee and the patent challenger." *Id.* at 2234-35. As a result of this sharing of the rewards from avoiding competition, "[t]he patentee and the challenger gain" but "the consumer loses." *Id.* at 2235.

As in *Actavis*, plaintiffs here allege that Warner Chilcott used side business deals that "in substance" offered reverse payments to induce generic competitors Watson (now Actavis) and Lupin to drop their patent challenges. Plaintiffs allege that, among other compensation mechanisms, Warner Chilcott induced Watson to stay out of the market for a defined period by promising that, once Watson (the first generic applicant on Loestrin 24) finally did enter, Warner Chilcott would not compete against Watson with an AG version of Loestrin 24 for six months.

In September 2014, the district court granted defendants' motions to dismiss the complaints, holding that reverse payments trigger antitrust scrutiny under *Actavis* only if they are in cash. According to the court, *Actavis* "fixates on the one form of consideration that was at issue in that case: cash." Slip op. at 17. But the court emphasized that its decision to grant the motion to dismiss was "a close call" (*id.* at 30) and termed the conclusion that *Actavis* applies only to cash payments

"vexing" (*id.* at 26, 28). The court recognized that its holding would give drug companies "the obvious cue to structure their settlements in ways that avoid cash payments" but achieve the same anticompetitive ends. *Id.* at 25, 28. "When a patent holder pays a would-be generic competitor to stay out of the market — regardless of the form of the payment — value is exchanged and the brand manufacturer is able to continue on with fewer competitors." Slip op. at 30.

The district court acknowledged that court opinions have "diverge[d]" on whether reverse payments are limited to cash. *Id.* at 31. In fact, nine courts have addressed the issue. Seven have ruled that a reverse payment need not necessarily be cash, while only one agreed with the district court here. *See In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516-SRU, Order on Motion to Dismiss (D. Conn. Mar. 23, 2015) (cash not required); *United Food and Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, No. 14-md-02521-WHO, Order on Motion to Dismiss (N.D. Cal. Nov. 17, 2014) (same); *In re Effexor EX Antitrust Litig.*, No. 3:11-cv-05479-PGS, Order on Motion to Dismiss (D.N.J. Oct. 6, 2014) (same); *Time Ins. Co. v. AstraZeneca*, No. 2:14-cv-04149-GAM, Order on Remand (E.D. Pa. Oct. 1, 2014) (same); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389-PGS, Order on Motion to Dismiss (D.N.J. Sept. 12, 2014) (same); *In re Niaspan Antitrust Litig.*, No. 2:13-md-2460-JD, Order on Motion to Dismiss (E.D. Pa. Sept. 5, 2014) (same); *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 1:12-md-

02409-WGY, Order on Motion to Dismiss (D. Mass. Sept. 11, 2013) (same); *but see In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-cv-995-WHW, Order on Motion for Reconsideration (D.N.J. Jan. 24, 2014) (cash required), *appeal pending*, No. 14-1243 (3d Cir.) .

SUMMARY OF ARGUMENT

As *Actavis* confirms, patent settlements enjoy no broad antitrust immunity and are subject to traditional antitrust principles. It is a core antitrust principle that commercial rivals may not collude to maintain supracompetitive prices by allocating markets or otherwise agreeing not to compete. The district court here, however, concluded that an anticompetitive patent-settlement agreement avoids scrutiny under traditional antitrust rules unless the reverse payment at the center of the agreement takes the form of cash. Slip op. at 17, 26. That holding contradicts the central logic of *Actavis* and makes no economic sense.

First, *Actavis* did not even suggest, let alone hold, that antitrust scrutiny extends only to cash-based reverse-payments; rather, the Court explained that traditional antitrust analysis applies broadly to "patent-related settlement agreements" and "overly restrictive patent licensing agreements." 133 S. Ct. at 2231-34. Non-cash reverse payments can have all of the same anticompetitive effects that, under *Actavis*, properly subject such payments to antitrust scrutiny. Specifically, they can enable commercial rivals, at the expense of consumers, to

maintain "supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market — the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id.* at 2236. Nothing in the *Actavis* decision suggests that the law governing such arrangements depends on the precise form of the compensation paid to achieve that "anticompetitive consequence." To the contrary, the reasoning in *Actavis* cuts squarely against that conclusion.

Second, the district court's logic violates the basic precept that antitrust liability principles turn on economic substance, not form. In particular, the court elevated form over economic substance when it concluded that reverse payments can trigger antitrust scrutiny only when they are made in cash rather than in the form of some non-cash economic equivalent. Its rationale would perversely allow parties settling patent litigation to avoid antitrust liability simply by sharing their enhanced monopoly profits in some form other than cash. But whether such sharing takes the form of gold bullion, stocks, free goods, real estate, or (as here) an additional agreement not to compete, the potential economic impact is the same — the drug companies benefit but consumers are harmed.

Finally, a settlement with a No-AG commitment can violate the antitrust laws whether it is characterized as a reverse payment (in kind rather than in cash) or alternatively as a reciprocal agreement not to compete. As *Actavis* confirms,

mutual non-compete agreements involving patents, including this one, are subject to rule-of-reason scrutiny.

ARGUMENT

I. UNDER *ACTAVIS*, PATENT LITIGATION SETTLEMENTS ARE SUBJECT TO TRADITIONAL ANTITRUST SCRUTINY REGARDLESS OF PAYMENT FORM

As the district court acknowledged, *Actavis* rejected the scope-of-the-patent test in favor of the "commonly applied" rule-of-reason analysis. Slip op. at 16. But the district court nonetheless refused to apply such scrutiny to *this* potentially anticompetitive reverse payment on the theory that *Actavis* "fixates on the one form of consideration that was at issue in that case: cash." Slip op. at 17. That rationale is wrong. As the district court appeared to recognize (slip op. at 17-19), the *Actavis* opinion did not "fixate" on "cash" because the Court attributed any legal significance to that form of reverse payment; instead, it mentioned money because the payments in that particular case happened to take the form of cash.[9] As another district court has explained, nothing in *Actavis* "require[s] some sort of monetary transaction to take place for an agreement between a brand and generic

[9] In fact, the reverse payment alleged in *Actavis* included a co-promotion agreement similar to the settlement in this case, yet the district court here held that even that agreement did not qualify for rule-of-reason scrutiny. That holding is impossible to square with *Actavis*. This brief focuses on the No-AG commitment as a clear case of non-cash compensation.

manufacturer to constitute a reverse payment." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

More fundamentally, confining *Actavis* to cases involving cash transfers would contradict the Supreme Court's precedential rationale for its holding. The Court relied heavily on prior decisions in which it had found settlement agreements anticompetitive and unlawful even though they involved no cash payment to the allegedly infringing party. *Actavis*, 133 S. Ct. at 2232-33; *see, e.g.*, *United States v. New Wrinkle*, 342 U.S. 371, 377-78 (1952) (patent licenses granted under a settlement agreement could violate the antitrust laws if they are the means by which patent holders jointly regulate distribution and control prices). The *Actavis* Court's reliance on those precedents would make no sense if the Court had intended its ruling to apply only to a narrow range of cases where the payment is in cash.

Moreover, the *Actavis* framework is well equipped to evaluate whether non-cash compensation amounts to an unlawful reverse payment. As describe in *Actavis*, the analysis of these kinds of litigation settlements "considers traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances,

such as here those related to patents." *Actavis*, 133 S. Ct. at 2231.[10] The Court explained that this approach applies generally to antitrust cases challenging "patent-related settlement agreements" and "overly restrictive patent licensing agreements." *Id.* at 2231-34; *see also id.* at 2237. The Court directed district courts to determine whether "the specific restraint at issue has the 'potential for genuine adverse effects on competition.'" *Id.* at 2234 (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986)); *see also Actavis* at 2237.

Additionally, if the rule-of-reason analysis prescribed by *Actavis* applied only to cash settlements, the parties in *Actavis* itself could have avoided antitrust scrutiny altogether simply by replacing their cash payments with some non-cash consideration of equivalent value, such as bonds, museum art, or real property. And all future parties contemplating anticompetitive reverse-payment agreements could evade the holding of *Actavis* simply by choosing some non-cash equivalent as compensation. But antitrust principles are not so easily evaded. Substituting one form of consideration for another does not protect consumers from the harms of anticompetitive agreements between competitors, nor does it alter the analysis.

[10] The federal enforcement agencies' 1995 *Antitrust Guidelines for the Licensing of Intellectual Property* also reflect this approach. *See* U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property*, 7-8 (Apr. 6, l995), http://www.justice.gov/atr/public/guidelines/0558.pdf.

"[S]ubstance, not form," governs the antitrust inquiry. *American Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 195 (2010).

The district court likewise violated a core holding of *Actavis* when it elevated the "public policy favor[ing] the settlement of patent litigation" over antitrust concerns in all cases involving non-cash reverse payments in order to "preserv[e] for litigants a viable path to resolve their disputes." Slip op. at 25-26. As the Supreme Court explained, however, litigants already have viable settlement paths that do *not* generally pose antitrust concerns, such as agreements that merely fix a date of generic entry. *See Actavis*, 133 S. Ct. at 2237; *see also* p. 11, *supra*. In contrast, when a settlement agreement *does* involve "large and unjustified" compensation by the brand to the generic, the Supreme Court held without qualification that the "risk of significant anticompetitive effects" subjects such a settlement to traditional rule-of-reason analysis. *Actavis*, 133 S. Ct. at 2237. That categorical conclusion forecloses the district court's reliance on the "desirability of settlements" as a basis for immunizing settlements in which compensation to the generic takes forms other than cash.

Finally, the Supreme Court did not, as the district court suggested, prescribe a multi-step analysis in which patent litigation settlements are scrutinized under the rule of reason only if the plaintiff has first alleged a reverse payment that is large and unjustified. *See* slip op. at 17, 26. In other words, the *Actavis* holding is not a

special rule that applies only after the plaintiff has made some kind of threshold showing. Rather, the inquiry into whether the payment is "large" and "unexplained" is part of the rule-of-reason analysis itself. *Actavis*, 133 S. Ct. at 2236, 2237.[11] *See also King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2015 U.S. Dist. LEXIS 9545, at *50 (E.D. Pa. Jan. 28, 2015) (rejecting argument that *Actavis* imposes a "threshold burden" before rule-of-reason analysis applies and considering whether payment is large and unjustified under "standard rule of reason analysis"); *Nexium*, 968 F. Supp. 2d at 386-87, 392 (applying rule-of-reason to No-AG reverse payment settlement).

II. A NO-AG COMMITMENT RAISES ALL THE SAME ECONOMIC CONCERNS THAT THE *ACTAVIS* COURT IDENTIFIED AS A BASIS FOR ANTITRUST REVIEW

In rejecting antitrust scrutiny for non-cash reverse payments, the district court not only contradicted the reasoning of *Actavis*, but also adopted a distinction between cash and non-cash payments that makes no *economic* sense. As the Supreme Court has long emphasized, antitrust analysis turns on economic

[11] *See also id.* at 2238 ("[T]rial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic questions – that of the presence of significant unjustified anticompetitive consequences.").

substance, not form.[12] Here, it is not the form of the reverse payment that triggers antitrust concern, but the impact of that payment on consumer welfare. The No-AG commitment that Warner Chilcott gave to Watson illustrates how, in economic substance, a non-cash reverse payment is at least as worrisome as a cash one.

As the Supreme Court explained, "significant adverse effects on competition" can arise whenever a reverse payment (1) provides the generic challenger something that it could not have obtained had it won its litigation, *Actavis*, 133 S. Ct at 2231, 2233, and (2) allows the parties "to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market," *id.*at 2236.[13] The facts

[12] *See, e.g., American Needle, Inc.*, 560 U.S. at 195 ("substance, not form, should determine whether a[n] … entity is capable of conspiring") (quoting *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 773 n.21 (1984)); *The Podiatrist Ass'n, Inc. v. La Cruz Azul de Puerto Rico*, 332 F.3d 6, 14 (1st Cir. 2003) ("[w]e look at substance rather than form") (quoting *United States v. Sealy, Inc.*, 388 U.S. 350, 352-53 (1967)); *United States v. Delta Dental of R.I.*, 943 F. Supp. 172, 190 (D.R.I. 1996) ("'legal presumption that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law'") (quoting *Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451, 466-67 (1992)).

[13] The End-Payors' brief erroneously omits the second element: that, by avoiding competition, the payment enables the parties to extend and share monopoly profits. *See American Sales Co., et al. v. Warner Chilcott Co., LLC*, No. 14-2071, *et al.*, at 21 (Jun. 9, 2015). The FTC has recognized both elements before and after *Actavis* was decided. *See* Reply Brief for Petitioner, *FTC v. Actavis Inc.*, No. 12-416, at 9-10 (Mar. 18, 2013); Plaintiff FTC's Mem. in Opp'n to Defendants' Mot. to Dismiss, *FTC v. AbbVie Inc.*, No. 14-cv-5151, ECF No. 47, at 19-20 (E.D. Pa. Dec. 12, 2014). The End-Payors' brief (at 30) also incorrectly states that the FTC

alleged here satisfy both conditions.[14] The agreement in this case plainly gave Watson something it could not have won in the patent litigation: the ability to insulate its generic product from competition with the branded drug company's authorized generic. Moreover, as alleged, the agreement maintains supracompetitive prices in which Warner Chilcott and Watson both share.

Warner Chilcott paid for that agreement with an economically consequential No-AG commitment. Under the FDCA, a brand-name manufacturer may introduce an AG product at any time as a matter of right. Typically a brand does so shortly after generic entry, thus both siphoning substantial revenues from the first-filer during its 180-day exclusivity period and generating price-reducing competition. *See* pp. 7-8, 12-13, *supra*. When the brand agrees to forgo selling an AG, however, it essentially hands revenues it would have earned through AG sales back to the first-filer generic company and also enables that company to set prices at supracompetitive levels. In turn, the brand forgoes the profits it would have earned by launching an AG only because it has secured additional monopoly

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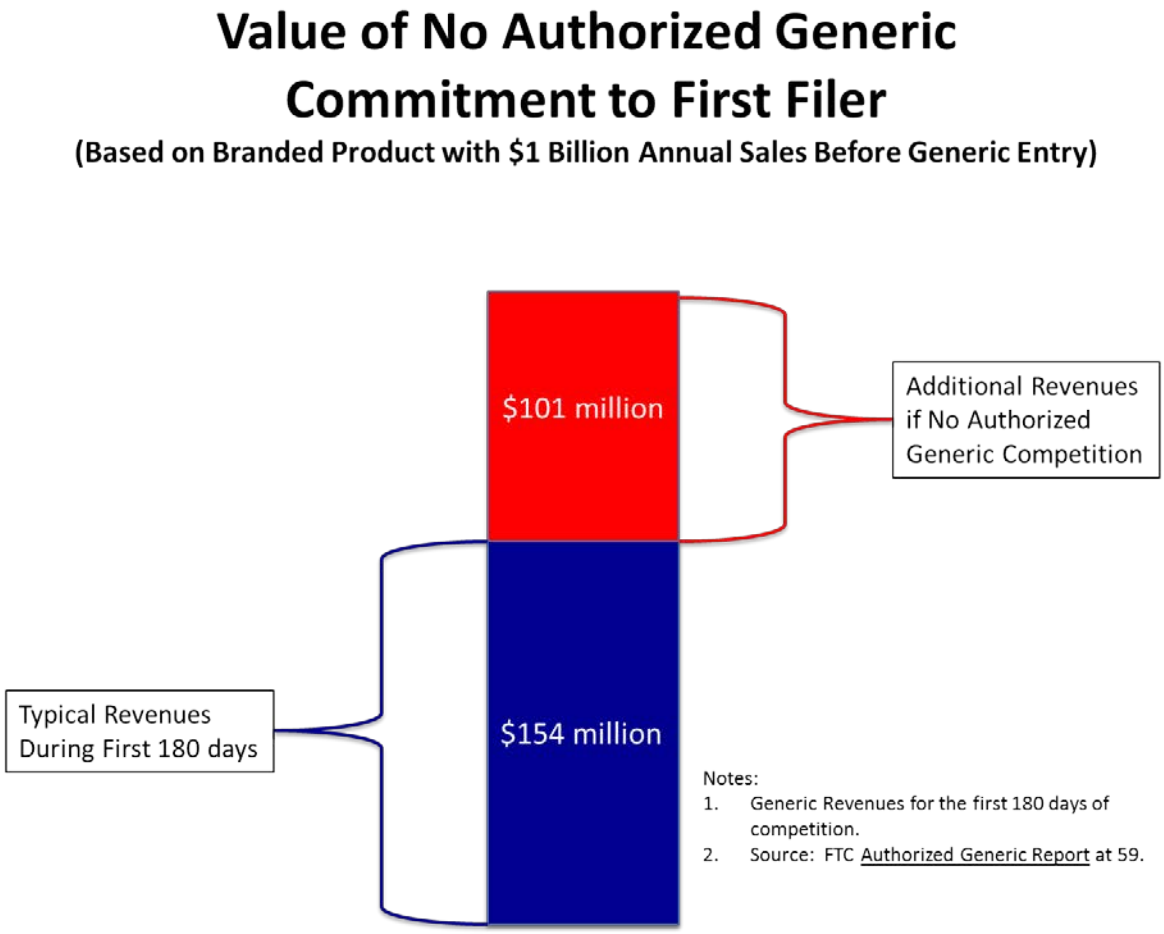
has described acceleration clauses in pharmaceutical settlements as analogous to "unlawful [most favored nation clauses]."

[14] As these criteria make clear, the district court was simply incorrect in suggesting that the only alternative to limiting "payment" to cash is to treat all types of consideration to the alleged infringer as a potentially unlawful compensation mechanism. Slip op. 23-24.

profits by inducing its first-filing rival to keep all generics off the market for an incremental period.

As noted, such No-AG commitments are highly valuable to the generic company. Typically, eliminating an AG during the first 180 days increases a first filer's revenue (such as Watson's in this situation) by approximately 65 to 100 percent. *AG Report* at 59. On a brand-name drug with one billion dollars in annual sales, the first filer will earn a conservatively estimated $255 million during the first 180 days of generic sales, if the branded-drug company agrees not to compete with an AG, but only $154 million, if an AG enters the market, a difference of $101 million:



These added revenues are not distinguishable in any economically significant way from the reverse payment analyzed in *Actavis*. The fact that the generic company obtains these additional revenues by selling its product does not make them comparable to the revenues that company would earn in a presumptively legal settlement in which the parties merely compromise on an entry date and the branded drug company pays no compensation to the generic. By giving up its unqualified right to earn profits from marketing its own AG product, the branded-drug company enables the generic to earn added revenues, thus

transferring economic value to the generic as surely as if it had written a check.[15] Either outcome raises the same antitrust concern: the possibility that the generic company agreed to stay out of the market for an incremental period in exchange for the payment. *See* pp. 14-15, *supra*.

Moreover, the district court was mistaken when it suggested that, unless a payment takes the form of cash, it is "all but impossible to assess the 'potential for genuine adverse effects on competition.'" Slip op. at 21 (quoting *Actavis*, 133 S. Ct. at 2234). Courts routinely determine compensation value of non-cash items in a variety of contexts, and the inquiry here is no less susceptible to judicial resolution. *See, e.g.*, *Baldwin v. Bader*, 585 F.3d 18 (1st Cir. 2009) (compensation paid through securities); *U.S. v. 33.92356 Acres of Land*, 585 F.3d 1 (1st Cir. 2009) (compensation for land). Determining this value can involve some estimation, but the fundamental principle is that non-cash items have an expected monetary value on which parties base decisions. In any given case, evidence obtained through discovery, including the parties' own documents or available data (or both), will

[15] Indeed, because a No-AG commitment can approximately double the revenues generated by the first-filer, the value might be more than the first-filer could have earned by prevailing in the patent litigation. *See AG Report* at vi.

enable the factfinder to estimate the value of a No-AG commitment or other non-cash form of consideration to permit the requisite rule-of-reason analsyis.[16]

Finally, characterizing a No-AG commitment as a form of "exclusive license," as the defendants here did below, does not change the analysis.[17] As the Court reiterated in *Actavis*, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly' — and consequently antitrust law immunity — that is conferred by a patent." 133 S. Ct. at 2231.[18] True, most

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[16] Although the district court believed that *Actavis* requires a court to assess the size and scale of the reverse payments relative to the brand's expected monopoly profits preserved by the agreement (slip op. at 19), the Supreme Court instead focused on whether the payment was sufficiently large to "induce the generic challenger to abandon its claim with a share of [the patentee's] monopoly profits that would otherwise be lost in the competitive market." 133 S. Ct. at 2235, 2236; *see also King Drug Co. of Florence*, 2015 U.S. Dist. LEXIS 9545, at *56 (rejecting the use of the brand's expected monopoly profits to determine whether a reverse payment is large).

[17] Defendants wrongly claimed below that the FTC took the position in *Actavis* that an exclusive license can never be a reverse payment. *See* Defendants' Reply Memorandum in Further Support of Motion to Dismiss at 22-23 (Apr. 23, 2014), Dkt. 97. But whether a particular exclusive license amounts to a reverse payment must be evaluated on its facts. The FTC has consistently characterized No-AG commitments to first-filers as payments, regardless of whether the commitment took the form of an exclusive license. *See*, *e.g.*, *AG Report* at 144-46.

[18] According to the leading antitrust treatise, cited by the Court in *Actavis*: "Assuming the patent is valid, the Patent Act expressly permits exclusive licenses, but this fact alone does not render them immune from antitrust scrutiny." 12 Phillip Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046, at 330 (3d ed. 2012) (footnotes omitted); *see also Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931) (applying rule-of-reason to cross-licensing agreements); *Orson, Inc. v.*

exclusive licenses in other contexts raise no antitrust concerns because they promote rather than reduce competition, such as by combining complementary assets.[19] Here, however, any "exclusive license" would simply take the form of a No-AG commitment, which does *not* promote competition and instead merely enlarges the pool of shared supracompetitive profits to the detriment of consumers.

III. RECIPROCAL AGREEMENTS NOT TO COMPETE CAN CAUSE ANTICOMPETITIVE HARM AND MAY VIOLATE THE ANTITRUST LAWS

As discussed, No-AG agreements are *at least* as worthy of antitrust scrutiny as agreements in which branded companies pay generic companies cash to stay out of the market. If anything, No-AG agreements raise even further antitrust concerns because they embody a *second, additional* agreement not to compete. In particular, No-AG commitments harm consumers first by inducing the generic to abandon its patent challenge and stay off the market for a period, and then by increasing generic prices *even after* generic entry by suppressing competition from an AG. See *AG Report* at ii-iii.

Miramax Film Corp., 79 F.3d 1358, 1372 (3d Cir. 1996) (subjecting exclusive licenses to rule of reason).

[19] U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property*, Section 3.1, at 7 (Apr. 6, 1995) ("While intellectual property licensing arrangements are typically welfare-enhancing and procompetitive, antitrust concerns may nonetheless arise.").

Such agreements can be viewed not only as reverse payments, but also as reciprocal agreements not to compete, which are independently subject to rule-of-reason scrutiny in this setting. *See Actavis*, 133 S. Ct. at 2237; *see also Standard Oil Co.*, 283 U.S. 163 (analyzing terms of patent settlement agreement under the rule of reason); *Moraine Products v. ICI America, Inc.*, 538 F.2d 134, 144-46 (7th Cir. 1976) (exclusive patent license subject to rule-of-reason analysis). Indeed, in *Actavis*, the Supreme Court cited its most recent precedent involving reciprocal agreements not to compete, *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990), in framing the key question about reverse-payment agreements — "whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws." *Actavis*, 133 S. Ct. at 2227.

In this case, the plaintiffs have alleged that Warner Chilcott and Watson entered into reciprocal agreements not to compete. At the time of the settlement, Warner Chilcott faced a risk of competition from Watson, and Watson faced a risk of authorized-generic competition during its exclusivity period. Under the settlement, Watson agreed not to compete against Warner Chilcott for Loestrin 24 from January 2009 to January 2014, and Warner Chilcott agreed not to market a generic form of Loestrin 24 in competition with Watson from January 2014 to July 2014. Direct Purchaser Compl. ¶ 163, End-Payor Compl. ¶ 88 (Watson agreed not to market generic until January 2014); Direct Purchaser Compl. ¶ 165, End-Payor

Compl. ¶ 90 (Warner Chilcott agreed not to launch AG until July 2014). When, as alleged here, each of those agreements allows the remaining competitor to charge supracompetitive prices, such agreements can violate the antitrust laws. As alleged, these are simply agreements by potential competitors to stay out of each other's backyard.

CONCLUSION

The Court should reverse the district court's decision and remand the case for further proceedings consistent with the Court's decision.

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